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| 09/940,682 | 08/27/2001 | David E. Townsend | 150026.464 | 4343 |

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| EXAMINER | |
|---|---|
| FORD, ALLISON M | |

| ART UNIT | PAPER NUMBER |
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| 1651 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/940,682 | TOWNSEND, DAVID E. | |
| | Examiner | Art Unit | |
| | ALLISON M. FORD | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,7,10-13,15 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,10-13,15 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicants' response of 11/17/2008 has been received and entered into the application file. Claims 1 and 25 have been amended; claims 2-6, 8, 9, 14, 16-24 and 26 are cancelled; claims 1, 7, 10-13, 15 and 25 remain pending in the current application, all of which have been considered on the merits. All arguments have been fully considered, and are each addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn/overcome.

### *Priority*

Acknowledgement is made of applicant's claim for priority to provisional application 60/228,956, filed 28 August 2000. This provisional application provides support for all claims; thus all claims are given the effective filing date of 28 August 2000.

Applicant's claim for the benefit as a CIP of prior-filed application US 08/484,593 (now US Patent 6,387,650) under 35 U.S.C. 120 is also acknowledged.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**(I)** With regards to the rejection of claims 1, 5, 7, 13, 15 and 16 under 35 USC 112, first paragraph, as lacking written description, Applicants have argued that the amendment to the claims to require inclusion of an antibiotic to suppress growth of non-target microorganisms in the sample would include an antibiotic which suppresses the growth of Gram positive microorganism; thus Applicants assert description is only needed of an aminopeptidase substrate which is acted upon by an aminopeptidase

present in substantially all Gram *negative* bacteria *except Campylobacter*; Applicants assert L-alanine peptidase satisfies this limitation, and a sufficient number of species of L-alanine aminopeptidase are disclosed in the current specification to provide written description for the claimed invention.

In response, it is respectfully submitted that the claims do not limit the antibiotic to an antibiotic that selectively suppresses Gram positive bacteria, thus the claims are not limited to a composition comprising a substrate for an aminopeptidase that is present in *substantially all* non-target *Gram negative* bacteria, *except Campylobacter* (the target microorganism). Therefore, Applicants are arguing limitations not in the presently examined claims. The currently claimed composition still requires a substrate for an aminopeptidase, wherein the aminopeptidase is absent from *Campylobacter*, but is present in substantially *all non-target* (all non-*Campylobacter*) microorganisms.

The point of contention is whether or not Applicants were in possession of an aminopeptidase substrate for an aminopeptidase that is absent from the target microorganism, but is present in *substantially all* non-target microorganisms. The present wording of the claims requires the aminopeptidase in question to be present in *substantially all* non-target microorganisms. The fact that Applicants have identified an aminopeptidase that is absent from *Campylobacter*, but is present in at least *some* other non-target microorganisms does not sufficiently support this limitation. Due to the great breath of the genus disclosure of "some" non-target microorganisms does not support the genus of "substantially all" non-target microorganisms. At this point it would appear to be remedial to simply delete the phrase "substantially all" from the phrase, leaving "... the signal moiety capable of providing a detectable signal when cleaved by non-target microorganisms in the sample...", this would function to limit the aminopeptidase (which defines the aminopeptidase substrate in the claimed composition) to one that is absent from the target microorganism (Applicants have supported that specific aminopeptidase are absent from select target microorganisms, such as L-alanine aminopeptidase being absent from *Campylobacter*), but is present in at least some other non-target microorganisms. This amendment would

obviate the rejection because the claims no longer require the aminopeptidase substrate to be cleaved by an aminopeptidase that is present in *substantially all* non-target microorganisms, but rather just *some* non-target microorganisms.

**At this point claims 1, 7, 10-13, 15 and 25 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed composition is interpreted as comprising, amongst other elements, a substrate for an aminopeptidase, wherein the aminopeptidase is substantially absent from the target microorganism, but is present in substantially all non-target microorganisms. The term "substantially all non-target microorganisms" is interpreted to include any and all microorganisms that are not the target microorganism Therefore in order to satisfy this limitation, the composition must include a substrate for an aminopeptidase, the aminopeptidase being absent from the target microorganism (*Campylobacter*), but *is* present in *substantially all other* microorganisms. The instant written description rejection is based on the fact that Applicants have not provided even a single example of an aminopeptidase or a corresponding substrate which meets this limitation.

It is noted the specification does disclose aminopeptidase which are absent from specific target microorganisms, *i.e.* L-alanine aminopeptidase being absent from *Campylobacter*; Applicants further provide disclosure of numerous substrates for these aminopeptidase. However, the specification does not support that the aminopeptidase identified as being absent from the target microorganism are present in substantially all non-target microorganisms. There is evidence that the aminopeptidase, *i.e.* L-alanine aminopeptidase is present in *some* non-target microorganisms, but not sufficient evidence to show that

particular aminopeptidase is present in *substantially all* non-target microorganisms. Therefore, there is not sufficient description to support that Applicants had identified any aminopeptidase which is absent from the target microorganism, but present in *substantially all* non-target microorganisms, and thus Applicants were not in possession of a substrate for such an unidentified aminopeptidase.

**(II)** With regards to the rejection of claims 1, 7, 10-13, 15 and 25 under 35 USC 112, first paragraph, as lacking enablement, Applicants have argued that the instant specification does provide sufficient guidance and teachings on how to successfully make and use the instant invention to detect *Campylobacter* microorganisms from mixed samples. Specifically Applicants assert the amended claims require inclusion of an antibiotic which would suppress the growth of Gram positive bacteria, and thus false positive readings would not be achieved. With regards to the aminopeptidase substrate, Applicants reiterate that the aminopeptidase must only be determined to be present in non-target microorganisms in the sample, not all microorganisms.

In response, it is again submitted that with regards to the antibiotic now required by the claims, Applicants are relying on limitations not in the presently examined claims: the current claims do not state the antibiotic suppresses the growth of Gram positive bacteria, rather the claims require the antibiotic to suppress growth of non-target microorganisms in general, no specificity as to the type of antibiotic, or action thereof is recited.

With regards to Applicants' arguments about the aminopeptidase substrate needing only to be specific for aminopeptidase present in non-target microorganisms in the sample, it is again reiterated that the rejection is based on the fact that Applicants have not identified a single aminopeptidase which would be reasonably expected to be present in *substantially all non-target* microorganisms, since the claims are not limited as to what kind of microorganisms may be present in a sample, Applicants cannot argue the

non-target microorganisms are narrower than all microorganisms which are not the target microorganism. Because Applicants have not identified any aminopeptidase substrate which meets the limitation of the current claims, it remains that Applicants have not enabled one to make or use the claimed invention. However, as discussed above, amendment the claims to delete "substantially all", leaving "... the signal moiety capable of providing a detectable signal when cleaved by non-target microorganisms in the sample..." would be remedial to obviate this part of the rejection.

**At this point claims 1, 7, 10-13, 15 and 25 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue or unreasonable experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). The key word is 'undue,' not experimentation.' " (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The claims are rejected as the disclosure fails to clearly teach or suggest a single aminopeptidase substrate which would satisfy the limitations of the current claims (a substrate for an aminopeptidase which is absent from the target microorganism, but present in *substantially all* non-target microorganisms); thus in order to determine and select an appropriate aminopeptidase substrate, it has been established that one would have to carryout an undue amount of experimentation, involving testing of virtually every microorganism for activity of every aminopeptidase. While methods for such testing

are routine, the quantity of experimentation necessary for a definite conclusion would be excessive and thus is considered undue. Thus the current disclosure does not enable one of ordinary skill to make the composition of the current claims, if one cannot make the composition, one cannot not use the composition.

***Claim Rejections - 35 USC § 103***

The rejections under 35 USC 103(a) are withdrawn due to the amendment to claims 1 and 25, specifically requiring inclusion of an antibiotic to suppress growth of non-target microorganisms. The primary reference Manafi et al does not teach including an antibiotic to suppress non-target microorganisms. Because Manafi et al intend only to identify microorganism samples as Gram positive or Gram negative, they do not intend to suppress growth of any microorganism, and thus inclusion of an antibiotic is not obvious in the composition of Manafi et al.

***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

**Applicant is advised that should claim 10 be found allowable, claim 25 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof.** When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the

allowed claim. See MPEP § 706.03(k). Claims 10 and 25 are identical in scope, because neither claim is allowable at this time, this is only a warning.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651